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Glenn P. Ladwig, Patent Attorney

REQUEST FOR CORRECTED

FILING RECEIPT Examining Group 1647 Patent Application

Docket No. EPI-104XC1 Serial No. 10/550.675

#### IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Art Unit : 1647

Applicants : Shabnam Tangri, Bianca Mothe, Alessandro Sette, Scott Southwood, Kristen

Briggs, Robert W. Chesnut

Serial No. : 10/550,675

Filed: September 26, 2005

Conf. No. : 8341

For : Peptides, Polypeptides, and Proteins of Reduced Immunogenicity and

Methods for Their Production

Commissioner for Patents

P.O. Box 1450

Alexandria, VA 22313-1450

### REQUEST FOR CORRECTED FILING RECEIPT

Sir:

The applicants respectfully request the correction of an error in the Filing Receipt for the above-identified patent application. Please send a corrected Filing Receipt with the following change:

## The Filing Receipt lists the Domestic Priority data of the application as:

This application is a 371 of PCT/US04/10353 04/02/2004 which claims benefit of 60/459,939 04/02/2003

#### The correct Domestic Priority data of the subject application is:

This application is a 371 of PCT/US2004/010353 04/02/2004 which claims benefit of 60/459,939 04/02/2003.

This application is also a CIP of 10/103,395 03/20/2002 which is a CON of 09/009,953 01/21/1998 which claims benefit of 60/036,713 01/23/1997 and 60/037,432 02/07/1997.

Attached is a copy of a Preliminary Amendment that was submitted when the subject application was filed amending the "Cross-Reference to Related Applications" section of the specification on page 1, line 6. Also attached is a copy of the executed Declaration under 37 C.F.R. §1.63, which was submitted to the Patent Office on May 18, 2006. A copy of the Filing Receipt containing the error is also attached.

Respectfully submitted,

Glenn P. Ladwig Patent Attorney Registration No. 46.853

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GPL/bra

Attachments: Copy of Preliminary Amendment

Copy of executed Declaration under 37 C.F.R. §1.63 Copy of Filing Receipt with error noted thereon



### INITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE United States Patent and Trademark Office Address COMMISSIONER FOR PATENTS FOR ESS 1439

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APPL NO	FILING OR 371(c) DATE	ART UNIT	FIL FEE REC'D	ATTY DOCKET NO	TOT CLMS	IND CLMS
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05/22/2006

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CONFIRMATION NO. 8341

HILING RECEIPT

OC000000023128329\*

Date Mailed: 03/29/2007

Receipt is acknowledged of this regular Patent Application. It will be considered in its order and you will be notified as to the results of the examination. Be sure to provide the U.S. APPLICATION NUMBER, FILING DATE, NAME OF APPLICATION NUMBER, FILING DATE, NAME OF APPLICANT, and TITLE OF INVENTION when inquiring about this application. Fees transmitted by check or draft are subject to collection. Please verify the accuracy of the data presented on this receipt. If an error is noted on this Filing Receipt, please mail to the Commissioner for Patents P.O. Box 1450 Alexandria Va 22313-1450. Please provide a copy of this Filing Receipt with the changes noted thereon. If you received a "Notice to File Missing Parts" for this application, please submit any corrections to this Filing Receipt with your reply to the Notice. When the USPTO processes the reply to the Notice, the USPTO will generate another Filing Receipt incorporating the requested corrections (if appropriate).

#### Applicant(s)

Shabnam Tangri, San Dlego, CA; Bianca Mothe, Oceanside, CA; Alessandro Sette, La Jolla, CA; Scott Southwood, Santee, CA; Kristen Briggs, Del Mar, CA; Robert W. Chesnut, Cardiff-by-the-Sea, CA;

Power of Attorney: The patent practitioners associated with Customer Number 23557.

Domestic Priority data as claimed by applicant

This application is a 371 of PCT/US04/10353 04/02/2004 which claims benefit of 60/459,939 04/02/2003
The present opplication is also a CIP of 10/103,395 03/30 (2002)
Continue Which is a CIP of 10/103,395 03/30 (2002)

Foreign Applications which is a CON of 09/009, 953 01/21/1998 which claims benefit of lub/034,713 01/23/1997 and 100/037,432 03/03/1997

If Required, Foreign Filing License Granted: 03/27/2007

The country code and number of your priority application, to be used for filing abroad under the Paris Convention, is US10/550,675

Projected Publication Date: 07/05/2007

Non-Publication Request: No

# IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

Docket No. : EPI-104XC1

Applicants : Shabnam Tangri. Bianca Mothe, Alessandro Sette, Scott Southwood,

Kristen Briggs, Robert W. Chesnut

For : Peptides, Polypeptides, and Proteins of Reduced Immunogenicity and

Methods for Their Production

MS PCT Commissioner for Patents P.O. Box 1450 Alexandria, VA 22313-1450



# PRELIMINARY AMENDMENT

Please amend the above-identified application as follows:



### In the Specification

Please replace paragraph [0001] on page 1 of the specification with the following paragraph:

[0001] This-application-This application is the National Stage of International Application Number PCT/US2004/010353, filed April 2, 2004, which claims benefit of priority under 35 U.S.C. §119(e)(1) to U.S. Provisional Patent Application No. 60/459,939, filed April 2, 2003 (each of which is hereby incorporated by reference in its entirety). The present application also is a continuation-in-part of U.S. Patent Application No. 10/103,395, filed March 20, 2002, which is a-continuation-in-part continuation of U.S. Patent Application No. 09/009,953, filed January 21, 1998, now U.S. Patent No. 6,413,517, issued July 2, 2002, which claims benefit of priority under 35 U.S.C. § 119(e)(1) to U.S. Provisional Patent Application Nos. 60/036,713, filed January 23, 1997 and 60/037,432 filed February 7, 1997, each of which is incorporated herein by reference in its entirety, including all amino acid and/or polynucleotide sequences, sequence listings, figures, claims, and tables.

Please replace paragraph [00170] on page 63 of the specification with the following paragraph:

[00170] For the present study, peptides were derived from the amino acid sequences of salmon calcitonin (amino acids 83-114 of P01263) (SEQ ID NO:4), human erythropoietin (amino acids 28-193 of P01588) (SEQ ID NO:3), human growth hormone 1 isoform 1 (amino acids 27-217 of P01241) (SEQ ID NO:5), human insulin alpha (amino acids 90-110 of P01308) (SEQ ID NO:6), human insulin beta (amino acids 25-54 of P01308) (SEQ ID NO:7), and human interferon beta (amino acids 22-187 of AAC41702) (SEQ ID NO:8) [see Figure-11].

Please replace paragraph [00253] on page 102 of the specification with the following paragraph:

[00253] To confirm that the EPO epitope analogs with disrupted HLA-DR binding affinity were less immunogenic, we utilized PBMC from 5 donors that had responded previously wild-type EPO and against the wild type EPO epitopes EPO 101 and EPO 136 and tested peptide combinations using the primary *In vitro* immunogenicity assay. In each case, we included one analog from the EPO 101 epitope, and one from of the EPO 136 epitope. These peptides were

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pooled in equimolar concentrations and tested; the wild-type epitopes EPO 101 and EPO 136 were also pooled at equimolar concentrations and used as positive controls. For each combination, the magnitude of responses net SFC and frequency of response in 10 individual cultures from each donor were recorded.—The data obtained are shown in Figure 12. Immunogenicity of the two wild-type EPO epitopes (EPO 101-115 and EPO 136-150) in the form of synthetic peptides, or EPO epitope analog combinations C2 (L102P and S146D), C3 (T107D and S146D) C4 (L102G, T107D and S146D) and C5 (L102S, T107D and S146D) were tested in primary in vitro induction assays. Ten individual cultures each from five different donors were tested.

Please delete paragraphs [0039] and [0040] on page 14 of the specification.

After page 137: Please insert as new page 138 the attached Abstract of the Disclosure.

# In the Drawings

Please insert the attached new pages 1-19 of drawings (Figures 1-10) after page 138 (Abstract of the Disclosure) of the application.

#### In the Claims

#### Claims 1-26 (Cancelled)

Claim 27 (New): A composition of matter comprising:

- a) an isolated or purified modified erythropoietin construct (MEC) selected from the group consisting of: SEQ ID NO: 10, SEQ ID NO: 11, SEQ ID NO: 12, SEQ ID NO: 13, SEQ ID NO: 14, and truncated modified erythropoietin constructs of lengths X to Y, wherein X is an integer selected from 1, 2, 3, 4, 5, or 6 and Y is an integer selected from 188, 189, 190, 191, 192, or 193; or
- an isolated or purified modified erythropoietin construct according to a), further comprising a heterologous polypeptide sequence; or
- c) an isolated MEC of a) or b), and a carrier or diluent; or
- an isolated, purified, or recombinant nucleic acid encoding a MEC according to a) or
   b); or
- e) an isolated, purified, or recombinant nucleic acid according to d), further comprising regulatory elements, vector elements, or other nucleic acid elements; or
- f) a host cell transformed with an isolated nucleic acid according to d) or e); or
- g) an isolated, purified or recombinant polynucleotide sequence comprising a sequence encoding a polypeptide sequence selected from the group consisting of SEQ 1D NO: 10, 11, 12, 13, 14, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 61, 62, 63, 64, 65, 66, 67, 68, 69, 70, 71, 72, 73, 74, 75, 76, 77, 78, 79, 80, 81, 82, 83, 84, 85, 86, 87, 88, 89, 90, 91, 92, 93, 94, 95, 96, 97, 98, 99, 100, 101, 102, 103, 104, 105, 106, 107, 108, 109, 110, 111, 112, 113, 114, 115, 116, 117, 118, 119, 120, 121, 122, 152, 153, 154, 155, 156, 157, 158, 159, 160, 161, 162, 163, 164, 165, 166, 167, 168, 169, 170, 171, 172, 173, 174, 175, 176, 177, 178, 179, 180, 181, 182, 183, 184, 185, 186, 187, 188, 189, 190, 191, 192, 193, 194, 195, 196, 197, 198, 199, 200, 201, 202, 203, 204, 205, 206, 207, 208, 209, 210, 211, 212, 213, 214, 215, 216, 217, 218, 219, 220, 221, 222, 223, 224, 225, 226, 227, 228, 229, 230, 231, 232, 233, 234, 235, 236, 237, 238, 239, 240, 241, 242, 243, and 244; or

- h) an isolated, purified or recombinant polynucleotide sequence comprising a complementary polynucleotide sequence to a polynucleotide sequence encoding a polypeptide sequence selected from the group consisting of SEQ ID NO: 10, 11, 12, 13, 14, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 61, 62, 63, 64, 65, 66, 67, 68, 69, 70, 71, 72, 73, 74, 75, 76, 77, 78, 79, 80, 81, 82, 83, 84, 85, 86, 87, 88, 89, 90, 91, 92, 93, 94, 95, 96, 97, 98, 99, 100, 101, 102, 103, 104, 105, 106, 107, 108, 109, 110, 111, 112, 113, 114, 115, 116, 117, 118, 119, 120, 121, 122, 152, 153, 154, 155, 156, 157, 158, 159, 160, 161, 162, 163, 164, 165, 166, 167, 168, 169, 170, 171, 172, 173, 174, 175, 176, 177, 178, 179, 180, 181, 182, 183, 184, 185, 186, 187, 188, 189, 190, 191, 192, 193, 194, 195, 196, 197, 198, 199, 200, 201, 202, 203, 204, 205, 206, 207, 208, 209, 210, 211, 212, 213, 214, 215, 216, 217, 218, 219, 220, 221, 222, 223, 224, 225, 226, 227, 228, 229, 230, 231, 232, 233, 234, 235, 236, 237, 238, 239, 240, 241, 242, 243, and 244; or
- i) an isolated, purified or recombinant polynucleotide sequence comprising a
  polynucleotide sequence having at least about 20% to 99.99% identity to a
  polynucleotide sequence of g) or h); or
- j) a fragment of a polynucleotide sequence according to g) or h); or
- k) a peptide, polypeptide, protein, or antibody having reduced immunogenicity as compared to the naturally occurring form of the peptide, polypeptide, or protein while retaining at least 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 61, 62, 63, 64, 65, 66, 67, 68, 69, 70, 71, 72, 73, 74, 75, 76, 77, 78, 79, 80, 81, 82, 83, 84, 85, 86, 87, 88, 89, 90, 91, 92, 93, 94, 95, 96, 97, 98, 99, or 100% of the biological activity of the unmodified or naturally occurring molecule and said reduced immunogenicity is the result of reduced binding to MHC Class II molecules; or
- a peptide, polypeptide, or protein according to k), wherein the peptide, polypeptide, or protein is a therapeutic peptide, polypeptide, protein or antibody used in the diagnosis or treatment of diseases, conditions, or disorders; or
- m) a peptide, polypeptide, protein, or antibody according to c) or k), wherein the peptide, polypeptide. or protein comprises all, or a portion of, IL-1, IL-2, IL-3, IL-4, IL-5, IL-6, IL-7, IL-8, IL-9, IL-10, IL-11, IL-15, IL-16, IL-18, IL-19, IL-23, IL-24, erythropoietin (EPO), insulin, human growth hormone, calcitomin, Factor VIII, G-

CSF, M-CSF, GM-CSF platelet derived growth factor (PDGF). MSF, FLT-3 ligand, EGF, fibroblast growth factor (FGF); human insulin alpha, human insulin beta, insulin-like growth factors; vascular endothelial growth factor (VEGF; interferons: leukemia inhibitory factor (LIF); ciliary neurotrophic factor (CNTF); oncostatin M: stem cell factor (SCF); transforming growth factors; chemokines, or antibodies selected from the group consisting of REMICADE® (Infliximab); REOPRO® (Abciximab); SIMULECT® (Basiliximab); ZENAPAX® (Daclizumab); HERCEPTIN® (Trastuzumab); SYNAGIS® (Palivizumab); and XOLAIR® (Omalizumab); or

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- n) a peptide, polypeptide, protein, or antibody according to m), wherein the protein is EPO and comprises a sequence selected from the group consisting of SEQ ID NOs: 10, 11, 12, 13, 14, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 152, 153, 154, 155, 156, 157, 158, 159, 160, 161, 162, 163, 164, 165, 166, 167, 168, 169, 170, 171, 172, 173, 174, 175, 176, 177, 178, 179, 180, 181, 182, 183, 184, 185, 186, 187, 188, 189, 190, 191, 192, 193, 194, 195, 196, 197, 198, 199, 200, 201, 202, 203, 204, 205, 206, 207, 208, 209, 210, 211, 212, 213, 214, 215, 216, 217, 218, 219, 220, 221, 222, 223, 224, 225, 226, 227, 228, 229, 230, 231, 232, 233, 234, 235, 236, 237, 238, 239, 240, 241, 242, 243, and 244; or
- o) an isolated, purified, or recombinant erythropoietin (EPO) polypeptide containing a substituted peptide segment, wherein said substituted peptide segment is located at positions G101-Q115 (SEQ ID NO: 40) or D136-R150 (SEQ ID NO: 47), and said substituted peptide segment contains at least one amino acid substitution: or
- p) an isolated protein of n), comprising an amino acid sequence selected from the group consisting of: SEQ ID NO:10; SEQ ID NO:11; SEQ ID NO:12; SEQ ID NO:13; SEQ ID NO:14; SEQ ID NO:152; SEQ ID NO:154; SEQ ID NO:155; SEQ ID NO:159; SEQ ID NO:162: SEQ ID NO:181; SEQ ID NO:187; SEQ ID NO:199; SEQ ID NO:225; SEQ ID NO:226; SEQ ID NO:227; SEQ ID NO:228; SEQ ID NO:229; and SEQ ID NO:233; SEQ ID NO:245; SEQ ID NO:246; and SEQ ID NO:247; or
- $q) \ \ apptide, polypeptide, protein, or antibody according to k), l), m), n), o), or p), and a \\ earrier or pharmaceutically acceptable excipient; or$
- r) an isolated, purified, or recombinant polynucleotide encoding a peptide, polypeptide,

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- protein and/or antibody according to k), l), m), n), o), or p); or
- an isolated, purified, or recombinant polynucleotide according to r), further comprising regulatory elements selected from promoters, enhancers, termination sequences, and combinations thereof; or
- a vector comprising an isolated, purified, or recombinant polynucleotide according to r) or s); or
- a host cell comprising an isolated, purified, or recombinant polynucleotide according to r), s), or t); or
- v) an isolated, purified, or recombinant EPO polypeptide according to 0), wherein said EPO polypeptide contains substituted peptide segments at positions G101-Q115 (SEO ID NO: 40) and D136-R150 (SEQ ID NO: 47); or
- w) an isolated, purified, or recombinant EPO polypeptide of o) or v), wherein said peptide segments are selected from those peptides set forth in Tables 10A, 10B, 11A, 11B, 12, 13A, 13B, 14A, 14B, or 14C; or
- x) an isolated, purified, or recombinant EPO polypeptide of claims o) or v), wherein said peptide segment is selected from the group consisting of: SEQ ID NO:152; SEQ ID NO:154; SEQ ID NO:155; SEQ ID NO:159; SEQ ID NO:162; SEQ ID NO:181; SEQ ID NO:187; SEQ ID NO:199; SEQ ID NO:225; SEQ ID NO:226; SEQ ID NO:227; SEQ ID NO:228; SEQ ID NO:229; and SEQ ID NO:233; SEQ ID NO:245; SEQ ID NO:246; and SEQ ID NO:247.

Claim 28 (New): A method of antagonizing an EPO receptor or a method of treating diseases or conditions associated with over-activation of the EPO receptor, comprising administering a composition comprising an EPO variant in amounts sufficient to: 1) block the binding of naturally occurring EPO to its receptor; or 2) reduce the activation levels of the EPO receptor, wherein the EPO variant comprises an amino acid sequence selected from the group consisting of SEQ ID NO: 10, 11, 12, 13, 14, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 61, 62, 63, 64, 65, 66, 67, 68, 69, 70, 71, 72, 73, 74, 75, 76, 77, 78, 79, 80, 81, 82, 83, 84, 85, 86, 87, 88, 89, 90, 91, 92, 93, 94, 95, 96, 97, 98, 99, 100, 101, 102, 103, 104, 105, 106, 107, 108, 109, 110, 111, 112, 113, 114, 115, 116, 117, 118, 119, 120, 121, 122, 152, 153, 154, 155, 156, 157, 158, 159, 160, 161, 162, 163, 164, 165, 166, 167, 168, 169, 170, 171, 172, 173, 174, 175,

176, 177, 178, 179, 180, 181, 182, 183, 184, 185, 186, 187, 188, 189, 190, 191, 192, 193, 194, 195, 196, 197, 198, 199, 200, 201, 202, 203, 204, 205, 206, 207, 208, 209, 210, 211, 212, 213, 214, 215, 216, 217, 218, 219, 220, 221, 222, 223, 224, 225, 226, 227, 228, 229, 230, 231, 232, 233, 234, 235, 236, 237, 238, 239, 240, 241, 242, 243, and 244, and wherein the EPO variant has the ability to bind to the EPO receptor and fails to activate the EPO receptor.

Claim 29 (New): A method of producing a recombinant peptide, polypeptide, protein or antibody comprising the culturing of a host cell according to claim 27 under conditions that allow for the expression of a recombinant peptide, polypeptide, protein or antibody.

Claim 30 (New): The method according to claim 29, further comprising the isolation of the recombinant peptide, polypeptide, protein and/or antibody from the host cell or culture system.

Claim 31 (New): A method for reducing a helper T lymphocyte (HTL) response against a candidate protein comprising: a) selecting a protein; b) analyzing the amino acid sequence of the protein for potential HTL epitopes; and e) modifying the amino acid sequence of the protein by removing the potential HTL epitope and thereby generating an analog protein.

Claim 32 (New): The method according to claim 31, further comprising conducting in vitro antigenicity analysis of said candidate protein using helper T-cells.

Claim 33 (New): An isolated, purified, or recombinant polynucleotide comprising a nucleic acid sequence encoding a polypeptide comprising an amino acid sequence selected from the group consisting of SEQ ID NO: 10, 11, 12, 13, 14, 20, 21, 22, 23, 24, 25, 26, 27, 28, 29, 30, 31, 32, 33, 34, 35, 36, 37, 38, 39, 40, 41, 42, 43, 44, 45, 46, 47, 48, 49, 50, 51, 52, 53, 54, 55, 56, 57, 58, 59, 60, 61, 62, 63, 64, 65, 66, 67, 68, 69, 70, 71, 72, 73, 74, 75, 76, 77, 78, 79, 80, 81, 82, 83, 84, 85, 86, 87, 88, 89, 90, 91, 92, 93, 94, 95, 96, 97, 98, 99, 100, 101, 102, 103, 104, 105, 106, 107, 108, 109, 110, 111, 112, 113, 114, 115, 116, 117, 118, 119, 120, 121, 122, 152, 153, 154, 155, 156, 157, 158, 159, 160, 161, 162, 163, 164, 165, 166, 167, 168, 169, 170, 171, 172, 173, 174, 175, 176, 177, 178, 179, 180, 181, 182, 183, 184, 185, 186, 187, 188, 189, 190, 191, 192, 193, 194, 195, 196, 197, 198, 199, 200, 201, 202, 203, 204, 205, 206, 207, 208, 209, 210,

211, 212, 213, 214, 215, 216, 217, 218, 219, 220, 221, 222, 223, 224, 225, 226, 227, 228, 229, 230, 231, 232, 233, 234, 235, 236, 237, 238, 239, 240, 241, 242, 243, 244, 245, 246, and 247.

# Remarks

Claims 1-26 were previously pending in the subject international patent application. By this amendment, claims 1-26 have been cancelled, and new claims 27-33 have been added. No new matter has been added by this Amendment. Support for this Amendment can be found throughout the specification and claims as originally filed. Accordingly, claims 27-33 are pending in the subject application.

By this Amendment, the applicants have also amended the specification to update the Cross-Reference to Related Applications section on page 1 and to add an Abstract of the Disclosure as new page 138. In addition, this amendment has been made in order to add pages 1-19 of the Drawings (Figures 1-10) to the application. Support for Figures 1-10 can be found in the provisional application (Serial No. 60/459,939, filed April 2, 2003), which is incorporated by reference at page 1, paragraph [0001], of the subject application in accordance with MPEP \$608.01(n) and \$2163.07(b). References to Figures 11 and 12 have been deleted. Some of the text of paragraph [0040] at page 14 of the specification has been added to paragraph [00253] at page 102. No new matter has been added by these amendments.

The Commissioner is hereby authorized to charge any fees under 37 CFR §§1.16, 1.17, or 1.492 as required by this paper to Deposit Account No. 19-0065.

Respectfully submitted,

Glenn P. Ladwig Patent Attorney

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Attachments: New Page 138 (Abstract of the Disclosure)

Pages 1-19 of drawings (Figures 1-10)

# Abstract of the Disclosure

The subject invention provides peptides, polypeptides, proteins and/or antibodies of reduced immunogenicity. Also provided are methods of reducing the immunogenicity of peptides, polypeptides, proteins and/or antibodies. In certain embodiments, the immunogenicity of therapeutic peptides, polypeptides, proteins, and/or antibodies such as hormones, growth factors, and cytokines is reduced.

### DECLARATION (37 C.F.R. § 1.63) AND POWER OF ATTORNEY

As a below-named inventor, I hereby declare that:

My residence, post office address, and citizenship are as stated below next to my name; and

I believe that I am the original, first, and sole inventor (if only one name is listed below), or an original, first, and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled Peptides, Polypeptides, and Proteins of Reduced Immunogenicity and Methods for Their Production, specification for which

☐ is attached hereto.

☑ was filed April 2, 2004, Serial No. PCT/US2004/010353 \_.

I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.

1 acknowledge the duty to disclose information which is material to the patentability of this application in accordance with Title 37, Code of Federal Regulations,  $\S$  1.56 (a).

I hereby claim foreign priority benefits under Title 35, United States Code §119 and/or §365 of any foreign application(s) for patent or inventor's certificate listed below and have also identified any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed.

Application	Country	Filing Date	Priority Claimed
Serial No.			

I hereby claim priority benefits under Title 35, United States Code §119 of any provisional application(s) for patent listed below:

Application Serial No.		
60/459,939	April 2, 2003	Yes
60/037,432	February 7, 1997	Yes
60/036,713	January 23, 1997	Yes

I hereby claim the benefit under Title 35, United States Code, §120 and/or §365 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the prior United States application(s) in the manner provided by the first paragraph of Title 35, United States Code, §112, 1 acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.56(a) which became available between the filling date of the prior application and the national or PCT international filing date of this application:

Application Serial No.	Filing Date	Status (Patented, Pending, Abandoned)
10/103,395	March 20, 2002	Abandoned
09/009,953	January 21, 1998	Patented

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of

Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

I hereby appoint the following persons registered to practice before the Patent and Trademark Office as my attorneys with full power of substitution and revocation to prosecute this application and all divisions and continuations thereof and to transact all business in the Patent and Trademark Office connected therewith who are associated with

### Customer Number 23557.

The attorneys/patent agents currently associated with this Customer Number are: David R. Saliwanchik, Reg. No. 31,794, Jeff Lloyd, Reg. No. 35,589, Doran R. Pace, Reg. No. 38,261; Jay M. Sanders, Reg. No. 39,355; Jean Kyle, Reg. No. 36,987; James S. Parker, Reg. No. 40,119; Frank C. Eisenschenk, Reg. No. 45,322; Gienn P. Ladwig, Reg. No. 46,833; Margaret Efron, Reg. No. 47,545; Gwendolyn L. Daniels, Reg. No. 51,594; John M. Sanders, Reg. No. 30,126; Jenna M. Morrison, Reg. No. 55,684; and Mai-Tram Dinh Lauer, Reg. No. 43,589.

I request that all correspondence be sent to:

Glenn P. Ladwig Saliwanchik, Lloyd & Saliwanchik A Professional Association PO Box 142950 Gainesville, FL 32614-2950

I further request that all telephone communications be directed to:

Glenn P. Ladwig 352-375-8100

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1	( <i>/</i>	46	4	Date	. Course 13 2005
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Name of Seventh Joint I	Inventor		
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Signature of Eighth Join	it inventor		

### DECLARATION (37 C.F.R. § 1.63) AND POWER OF ATTORNEY

As a below-named inventor, I hereby declare that:

My residence, post office address, and citizenship are as stated below next to my name: and

- I believe that I am the original, first, and sole inventor (if only one name is listed below), or an original, first, and joint inventor (if plural names are listed below) of the subject matter which is claimed and for which a patent is sought on the invention entitled Peptides, Polypeptides, and Proteins of Reduced Immunogenicity and Methods for Their Production, specification for which
  - is attached hereto.
    - was filed April 2, 2004, Serial No. PCT/US2004/010353
       .
- I hereby state that I have reviewed and understand the contents of the above-identified specification, including the claims, as amended by any amendment referred to above.
- I acknowledge the duty to disclose information which is material to the patentability of this application in accordance with Title 37, Code of Federal Regulations, § 1.56 (a).
- I hereby claim foreign priority benefits under Title 35. United States Code §119 and/or §365 of any foreign application(s) for patent or inventor's certificate listed below and have also identified any foreign application for patent or inventor's certificate having a filing date before that of the application on which priority is claimed:

Application	Country	Filing Date	Priority Claimed
Serial No.			

I hereby claim priority benefits under Title 35, United States Code §119 of any provisional application(s) for patent listed below:

Application	Filing Date	Priority Claimed
Serial No. 60/459,939	April 2, 2003	Yes
60/037.432	February 7, 1997	Yes
60/036 713	January 23, 1997	Yes

I hereby claim the benefit under Title 35, United States Code, §120 and/or §365 of any United States application(s) listed below and, insofar as the subject matter of each of the claims of this application is not disclosed in the pnor United States application(s) in the manner provided by the first paragraph of Title 35, United States Code, §112, I acknowledge the duty to disclose material information as defined in Title 37, Code of Federal Regulations, §1.5(a) which became available between the filing date of the prior application:

Application	Filing Date	Status (Patented,
Serial No.		Pending, Abandoned)
10/103,395	March 20, 2002	Abandoned
09/009,953	January 21, 1998	Patented

I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that wilfluf lafase statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of

Title 18 of the United States Code, and that such willful false statements may jeopardize the validity of the application or any patent issued thereon.

I hereby appoint the following persons registered to practice before the Patent and Trademark Office as my attorneys with full power of substitution and revocation to prosecute this application and all divisions and continuations thereof and to transact all business in the Patent and Trademark Office connected therewith who are associated with

### Customer Number 23557.

The attomeys/patent agents currently associated with this Customer Number are: David R. Saliwanchik, Reg. No. 31,794; Jeff Lloyd, Reg. No. 35,559; Doran R. Pacc. Reg. No. 38,261; Jay M. Sanders, Reg. No. 30,355; Jean Kyle. Reg. No. 10,5987; James S. Parker, Reg. No. 40,119; Frank C. Eisenschenk, Reg. No. 45,332; Glenn P. Ladwig, Reg. No. 46,833; Margaret Efron, Reg. No. 47,545; Gwendolyn L. Daniels, Reg. No. 51,594; John M. Sanders, Reg. No. 30,126; Jenna M. Morrison, Reg. No. 54,864; and Mai-Tram Dinh Lauer, Reg. No. 43,689.

I request that all correspondence be sent to:

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I further request that all telephone communications be directed to:

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Signature of S	Sixth Joint	Inventor			
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				Date	
Signature of	Seventh Jo	int Inventor			
Name of Eig	hth Joint Ir	ventor			
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					ALL PARTY OF THE P
				Date	
Signature of	Eighth Joi	nt Inventor			